1	UNITED STATES DISTRICT COURT		
2	MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION		
3 4	BARBARA ATKINS and CARSIE BALDWIN, as Next of Kin of Darren Lee Baldwin, deceased.		
5	Plaintiffs,		
6	·	NO	
7	VS.		
8	JANSSEN PHARMACEUTICA, INC.; JANSSEN, L.P.; ALZA CORPORATION; and DOES 1 through 10, inclusive.	DEMAND FOR JURY TRIAL	
9	Defendants.		
10			
11			
12			
13			
14	Plaintiff Barbara Atkins and Carsie Baldwin, as Next of Kin of Darren Lee Baldwin,		
15	hereby complains against Janssen Pharmaceutical, Inc.; Janssen, L.P.; ALZA		
16	Corporation.; and Does 1 through 10, and all	eges as follows:	
17			
18	DESCRIPTION OF THE PARTIES		
19	1. This action involves the wrongful death of Darren Lee Baldwin. Darren Lee		
20	Baldwin was a resident of Davidson County, Tennessee at the time of his death. Plaintiff		
21	Barbara Atkins is an individual residing in Rutherford County, Tennessee and is the		
22	surviving mother and Successor-in-Interest of Darren Lee Baldwin and is referred to		
23	herein as "Plaintiff." Carsie Baldwin is an individual residing in Rutherford County,		
24	Tennessee and is the surviving father and Successors-in-Interest of Darren Lee Baldwin		
25	are is referred to herein as "Plaintiff".		
26	2. Defendant Janssen Pharmaceutica, Inc., 1125 Trenton Harbourton Road,		
27	Titusville, New Jersey 08560 and Johnson & Johnson, Johnson & Johnson Plaza, New		
28	Brunswick, NJ 08933, is a limited partnersh	ip organized and existing under the laws of	
20			

Case 3:10-cv-00529 Document 1 Filed 05/28/10 Page 1 of 20 PageID #: 1

the State of New Jersey and with its principal place of business in the State of New Jersey. Janssen Pharmaceutica, Inc. is a global pharmaceutical company with market leading positions in generic pharmaceuticals, transdermal technology and unit dose packaged products. Janssen Pharmaceutica, Inc. does routine and substantial business in the State of Tennessee.

- Jersey 08560 and Johnson & Johnson & Johnson & Johnson Plaza, New Brunswick, NJ 08933, is a limited partnership organized under the laws of the State of New Jersey and with its principal place of business in the State of New Jersey. Janssen, L.P. is a global pharmaceutical company with market leading positions in generic pharmaceuticals, transdermal technology and unit dose packaged products. Janssen, L.P. does routine and substantial business in the State of Tennessee.
- 4. Defendant ALZA Corporation, 6500 Paseo Padre Parkway, Fremon, CA 94555, is a corporation organized under the laws of the State of Delaware and with its principal place of business in the State of California. ALZA Corp. is a global pharmaceutical company with market leading positions in generic pharmaceuticals, transdermal technology and unit dose packaged products. ALZA Corp. does routine and substantial business in the State of Tennessee.
- 5. The true names and/or capacities, whether individual, corporate associate, governmental or otherwise of defendants Does 1 through 10, inclusive and each of them are unknown to the Plaintiff, who therefore sue said defendants by such fictitious names. When the true names and or capacities of said defendants are ascertained, Plaintiff will seek leave of this Court to amend the Complaint accordingly.
- 6. Plaintiff is informed and believes, and based thereupon alleges, that each defendant designated herein as a Doe was responsible, negligently or in some other actionable manner, for the events and happenings herein referred to which proximately caused the damages to the Plaintiff as hereinafter alleged, either through said

defendant's own negligence or through the conduct of its agents, servants, employees or representatives in some other manner.

- 7. Plaintiff is informed and believes, and based thereupon alleges that at all times mentioned herein each of the defendants, including Defendant Does 1 through 10, inclusive, and each of them were the agents, servants, employees, and/or representatives of each of the remaining defendants and were at all times material hereto acting within the authorized course and scope of said agency, service, employment and/or representation, and/or that all of said acts, conduct and omissions were subsequently ratified by their respective principals and the benefits thereof accepted by such principals.
- 8. Defendants Janssen Pharmaceutica, Inc., Janssen, L.P., ALZA Corporation, and Does 1-10 will be referred to herein, collectively, as "Defendants".
- 9. At all times relevant hereto, Defendants were engaged in the business of the marketing, selling, distributing and/or promoting the "Fentanyl Transdermal System" (referred to herein as the "Fentanyl Patch") throughout the United States and specifically in the State of Tennessee. At all times relevant to this case, Defendants were doing business in Tennessee as the manufacturer, seller, distributor and promoter of the Fentanyl Patch. Defendants are subject to suit in this jurisdiction in this wrongful death case.
- 10. Defendants manufactured, sold, distributed and promoted the Fentanyl Patch at issue in this litigation. Defendants placed the defective and leaking Fentanyl Patch at issue in the national stream of commerce resulting in its sale in Tennessee to the Plaintiff's decedent, Darren Lee Baldwin.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a), because this action, which has an amount in controversy in excess of \$75,000, is between citizens of different states.

- 12. This is a proper venue, pursuant to 28 U.S.C. § 1391(a), because it is the District in which a substantial part of the events or omissions giving rise to the claim occurred and is Defendants' residence for purposes of 28 U.S.C. § 1391(c).
- 13. The Court has specific and general personal jurisdiction over all Defendants because they purposely availed themselves of the privilege of conducting activities within Tennessee; they have substantial and continuous contacts with the State of Tennessee, generally and with respect to this action, to satisfy both general and specific minimum contacts; and exercising jurisdiction over them does not offend the traditional notions of fair play and substantial justice.

FACTUAL ALLEGATIONS

- 14. Fentanyl Transdermal System is the registered name for a transdermal patch, which is available only by prescription. This patch contains fentanyl, a synthetic opioid that is up to one hundred times as strong as morphine.
- 15. The Fentanyl Patch is applied directly to the skin of the user, and is supposed to deliver this strong pain medicine at a regulated rate for up to seventy-two (72) hours. The Fentanyl Patch is supposed to be prescribed to relieve chronic moderate to severe pain, such as that which was suffered by Plaintiff's decedent, Darren Lee Baldwin.
- 16. At all relevant times, Defendants were in the business of designing, licensing, promoting, manufacturing, marketing, selling and distributing pharmaceuticals and other products, including Fentanyl Patches. Defendants do business, and do business by agent, in the State of Tennessee. At all relevant times, Defendants designed, developed, licensed, marketed, manufactured, sold and placed in the steam of commerce Fentanyl Patches, including the patch at issue in this lawsuit.
- 17. The Fentanyl Patch in question was designed, manufactured, distributed, sold and placed in the stream of commerce by the Defendants. The patch is designed to be placed on the skin of the user and to be worn for a period of seventy-two (72) hours.

In theory, the fentanyl in the patch will then be introduced to the user at a controlled rate over this period of time.

- 18. Defendants knew, or had reason to know, before the date decedent Darren Lee Baldwin used the patch in question, that there was a danger or risk that patches could deliver a greater than stated amount of fentanyl or otherwise cause an excessive and deadly amount of fentanyl to enter the body of the person using the patch.
- 19. The Defendants took inadequate steps to advise consumers, including decedent, Darren Lee Baldwin, of this danger and the significant risks it presented to those using the patch.
- 20. The Fentanyl Patch used by Darren Lee Baldwin on or about February 28, 2005 was defective in that it allowed an excess amount of fentanyl to come into contact with the decedent's skin or otherwise caused or allowed an excessive amount of fentanyl to enter his body, resulting in his death. As a result of using said Fentanyl Patch, Darren Lee Baldwin received an overdose of the opioid fentanyl and died as a direct and proximate result.
- 21. Plaintiff alleges that Defendants were aware of the dangers and risks presented to those persons using the Fentanyl Patches referred to herein and that these Defendants aided, abetted, ratified, authorized, and acted in concert in the wrongful conduct set forth herein.
- 22. The Defendants have widely promoted the use of Fentanyl Patches as a safe and effective method of dealing with chronic pain. This included representations about the safety and effectiveness of using the Fentanyl Patches they designed, manufactured and sold.
- 23. The Defendants, individually and/or collectively, had a significant financial incentive to suppress, misrepresent and/or conceal any potential dangers or risks associated with using their Fentanyl Patches.
- 24. Plaintiff asserts that Defendants acted for the purpose of maximizing profits at the expense of the health of Darren Lee Baldwin, and the health of others using

Fentanyl Patches. Plaintiff further asserts that these Defendants had actual or constructive knowledge that a percentage of the patches they placed into the stream of commerce were defective and posed a significant danger to anyone who used these patches, yet failed to take adequate or timely actions to ensure that potential users of these patches were advised of the defects and warned not to use the patches.

- 25. Defendants acted with a profit motive, in failing to adequately or appropriately disclose material information relating to the defects in Fentanyl Patches. As a result, users of these patches, including Darren Lee Baldwin, were unaware of the dangers involved in using these Fentanyl Patches, and were therefore unable to avoid injury caused by using these patches.
- 26. On or about February 28, 2005, Darren Lee Baldwin applied the Fentanyl Patch at issue in this action as directed and in compliance with the prescription for the patch. That same day, Darren Lee Baldwin died.
- 27. The untimely death of Darren Lee Baldwin deprived his mother, Barbara Atkins and his father, Carsie Baldwin of the ongoing love, society, assistance, and support they enjoyed. His death likewise deprived them of the income and financial support he had historically provided and would continue to provide to them in the years to come.

FIRST CAUSE OF ACTION

(Negligence)

- 28. Plaintiff realleges and incorporates herein the above Paragraphs as though fully set forth herein.
- 29. Defendants designed, manufactured, marketed and distributed for profit the Fentanyl Patch that proximately caused the decedent's death. Defendants specifically and purposefully sold the Fentanyl Patch throughout the United States, including Tennessee, to retailers.

- 30. Defendants designed, manufactured, distributed, marketed and placed in the stream of commerce the fentanyl dispensing Fentanyl Patch, which proximately caused decedent's death.
- 31. At all times herein mentioned, Defendants had a duty to properly research, design, formulate, compound, test, manufacture, produce, process, assemble, inspect, distribute, market, label, promote, package, advertise, prepare for use, sell, prescribe and adequately warn of the risks and dangers of their Fentanyl Patch.
- 32. At all times herein mentioned, Defendants failed to exercise ordinary care and negligently and carelessly researched, designed, formulated, compounded, tested, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised, prepared for use and sold their Fentanyl Patches and failed to adequately test and warn of the risks and dangers of these Fentanyl Patches.
- 33. At all times herein mentioned, Defendants failed to investigate thoroughly and promptly report any problems or defects with their Fentanyl Patches, or adverse reactions and side effects experienced by those using their Fentanyl Patches and did not report same to the appropriate authorities and to make the information available to the public, including the decedent herein.
- 34. After learning of problems with their Fentanyl Patches and knowing that injuries and deaths had occurred, or could occur, as a result of the use of their Fentanyl Patches, the Defendants negligently failed to issue warnings, stop further sales or distribution, issue a recall, or take any steps to publicize or alert the users of their Fentanyl Patches to the problems, risks or dangers of using these patches.
- 35. As a result of said negligence and carelessness of Defendants, Darren Lee Baldwin was caused to suffer a fatal overdose of the potent opioid, fentanyl, resulting in his death. As a direct and legal result of the conduct of defendants, and each of them, severe and permanent injuries and damages were caused thereby to Plaintiff and Plaintiff's decedent, including expenses for medical care, loss of earnings and earning

capacity, loss of financial support, and loss of love, care, comfort, society, moral, assistance, and support, all in turn legally resulting in Plaintiff's special and general damages in a sum in excess of the minimum subject matter jurisdiction of this Superior Court according to proof at trial.

SECOND CAUSE OF ACTION

(Strict Product Liability)

36. Plaintiff realleges and incorporates the above Paragraphs as though fully set for herein.

37. The Fentanyl Patch in question was originally formulated, designed, manufactured, and sold by Defendants.

38. At the time the Fentanyl Patch in question was sold, Defendants were in the business of formulating, designing, manufacturing, and selling products such as the one in question and knew that it would be used without inspection for defects.

39. At the time the Fentanyl Patch in question was formulated, designed, manufactured, and sold by Defendants, it was defective in formulation, design, and manufacture, and the defective formulation, design, and manufacture of the Fentanyl Patch was a substantial factor in causing the incident, the death of Darren Lee Baldwin,

and Plaintiffs damages.

21

22

23

25

26

27

40. The defective formulation and design of the Fentanyl Patch caused it to fail to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the risks of danger inherent in the design outweighed the benefits of the design or formulation. Alternatively, these Fentanyl Patches, as manufactured and/or supplied by the Defendants were defective in design and/or formulation in that when such drug was placed in the stream of commerce, it was unreasonably dangerous, was more dangerous than an ordinary consumer would expect, and more dangerous than other forms of treatment for pain.

- 41. There were safer alternative designs or formulations other than the one used, which were economically and technologically feasible and would have prevented or significantly reduced the risk of accident and/or injury in question without substantially impairing the product's utility. These safer alternative designs and formulations were available in the market and were technologically and economically feasible at the time the Fentanyl Patch was manufactured and would not have impaired the utility of the product.
- 42. At the time the Fentanyl Patch in question left the Defendants' possession, it was defective in manufacture, as it deviated from Defendants' design specifications, intended result, and/or from other seemingly identical products from Defendants. The defective manufacture of the Patch was a substantial factor in bringing about the incident, the death of Darren Lee Baldwin, and Plaintiff's damages.
- 43. Based upon information and belief, the Defendants actually knew, or should have known, of the defective and unsafe nature of their Fentanyl Patches, but continued to defectively design, manufacture, market and sell these Fentanyl Patches so as to maximize sales and profits at the expense of public health and safety, in conscious disregard of the foreseeable harm caused by their Fentanyl Patches.
- 44. At the time of the incident, the Fentanyl Patch was in substantially the same condition as it was at the time it was placed into the stream of commerce. No material alterations were made to the product. At the time of the incident, the product was in the same or substantially similar condition as when it left the control of Defendants.
- 45. As a result of said negligence and carelessness of Defendants, Darren Lee Baldwin was caused to suffer a fatal overdose of the potent opioid, fentanyl, resulting in his death. As a direct and legal result of the conduct of defendants, and each of them, severe and permanent injuries and damages were caused thereby to Plaintiff and Plaintiff's decedent, including expenses for medical care, loss of earnings and earning capacity, loss of financial support, and loss of love, care, comfort, society, moral,

assistance, and support, all in turn legally resulting in Plaintiff's special and general damages in a sum in excess of the minimum subject matter jurisdiction of this Superior Court according to proof at trial.

THIRD CAUSE OF ACTION

(Failure to Warn)

- 46. Plaintiff realleges and incorporates the above referenced Paragraphs as though fully set forth herein.
- 47. The Fentanyl Patch in question was originally formulated, designed, manufactured, marketed, and sold by Defendants.
- 48. At the time the Fentanyl Patch in question was sold Defendants were in the business of formulating, designing, manufacturing, marketing, and selling products such as the one in question and knew that it would be used without inspection for defects.
- 49. At the time the Fentanyl Patch in question was formulated, designed, manufactured, marketed and sold by Defendants, it was defective in marketing, labeling, promotion, packaging and advertising, in that, and not by way of limitation, said product and its warnings, instructions and directions failed to warn of the dangerous and defective propensities of these Fentanyl Patches, which risks were known or by the application of reasonably developed human skill and foresight should have been known by Defendants, and each of them. Defendants, and each of them, failed to give adequate instructions/warnings to avoid such dangers, which failure rendered the product unreasonably dangerous as marketed.
- 50. The Defendants failed to perform adequate testing that would have shown that their Fentanyl Patches possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made-both with respect to the use of this delivery system for the drug, fentanyl.
- 51. The Fentanyl Patches designed, manufactured and/or supplied by the Defendants were defective due to inadequate post-marketing warnings or instructions

because, after the Defendants knew or should have known of the risks of injury or death from the use of their Fentanyl Patches, they failed to provide adequate warnings to users or consumers of the product and continued to aggressively promote their Fentanyl Patches as a safe and effective means of pain management.

- 52. At all times noted herein, the Fentanyl Patches were defective, and the Defendants knew that the products were to be used by the user without inspection for defects therein. Moreover, Darren Lee Baldwin neither knew, nor had reason to know at the time of his use of the Fentanyl Patch at issue that it was defective.
- 53. As a result of said negligence and carelessness of Defendants, Darren Lee Baldwin was caused to suffer a fatal overdose of the potent opioid, fentanyl, resulting in his death. As a direct and legal result of the conduct of Defendants, and each of them, severe and permanent injuries and damages were caused thereby to Plaintiff and Plaintiff's decedent, including expenses for medical care, loss of earnings and earning capacity, loss of financial support, and loss of love, care, comfort, society, moral, assistance, and support, all in turn legally resulting in Plaintiffs special and general damages in a sum in excess of the minimum subject matter jurisdiction of this Superior Court according to proof at trial.

FOURTH CAUSE OF ACTION

(Breach of Express Warranty)

- 54. Plaintiff realleges and incorporates the above referenced Paragraphs as though fully set forth herein.
- 55. The Fentanyl Patch in question was originally formulated, designed, manufactured, marketed, and sold by Defendants.
- 56. At the time the Fentanyl Patch in question was sold, Defendants were in the business of formulating, designing, manufacturing, marketing, and selling products such as the one in question and knew that it would be used without inspection for defects.

- 57. At all times herein mentioned, Defendants expressly warranted to Darren Lee Baldwin and his physicians, by and through statements made by these Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public that their Fentanyl Patches were safe, effective, fit and proper for their intended use.
- 58. In utilizing the Fentanyl Patches, Darren Lee Baldwin relied on the skill, judgment, representations and foregoing express warranties of the Defendants. Said warranties and representations were false in that these Fentanyl Patches were not safe and were unfit for the uses for which they were intended.
- 59. As a result of said actions of Defendants, Darren Lee Baldwin was caused to suffer a fatal overdose of the potent opioid, fentanyl, resulting in his death. As a direct and legal result of the conduct of defendants, and each of them, severe and permanent injuries and damages were caused thereby to Plaintiff and Plaintiffs Decedent, including expenses for medical care, loss of earnings and earning capacity, loss of financial support, and loss of love, care, comfort, society, moral, assistance, and support, all in turn legally resulting in Plaintiffs special and general damages in a sum in excess of the minimum subject matter jurisdiction of this Superior Court according to proof at trial.

FIFTH CAUSE OF ACTION

(Breach of Implied Warranty)

- 60. Plaintiff realleges and incorporates the above referenced paragraphs as though fully set forth herein.
- 61. The Fentanyl Patch in question was originally formulated, designed, manufactured, marketed, and sold by Defendants.
- 62. At the time the Fentanyl Patch in question was sold, Defendants were in the business of formulating, designing, manufacturing, marketing, and selling products such as the one in question and knew that it would be used without inspection for defects.

- 63. Prior to the time that Darren Lee Baldwin used the Fentanyl Patch at issue, Defendants impliedly warranted to Darren Lee Baldwin and his physicians that said Fentanyl Patch was of merchantable quality and safe and fit for sustained, time-controlled pain management.
- 64. At all times the Defendants marketed, sold and/or distributed the Fentanyl Patch at issue and had actual or constructive knowledge of the particular purpose for which Darren Lee Baldwin would use the Fentanyl Patch.
- 65. Darren Lee Baldwin was unskilled in the research, design, testing, manufacturing, production, processing, formulation, compounding, assembling, inspection, distribution, marketing, labeling, promotion, packaging and advertising of Fentanyl Patches and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using the Fentanyl Patch at issue in this case.
- 66. Defendants breached an implied warranty of merchantability. Plaintiff alleges that the Fentanyl Patch at issue was not of merchantable quality, not fit, not safe, and not in proper condition for ordinary uses in which Fentanyl Patch was allegedly designed to be used. Plaintiff alleges that the Defendants breached this implied warranty of merchantability which breach directly and proximately caused Darren Lee Baldwin to suffer a fatal overdose of the potent opiod fentanyl resulting in his death.
- 67. The Fentanyl Patch at issue was neither safe for its intended use nor of merchantable quality, as warranted by the Defendants in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.
- 68. As a result of said actions of Defendants, Darren Lee Baldwin was caused to suffer a fatal overdose of the potent opioid, fentanyl, resulting in his death. As a direct and legal result of the conduct of defendants, and each of them, severe and permanent injuries and damages were caused thereby to Plaintiff and Plaintiffs Decedent, including expenses for medical care, loss of earnings and earning capacity, loss of financial support, and loss of love, care, comfort, society, moral, assistance, and support, all in

turn legally resulting in Plaintiffs special and general damages in a sum in excess of the minimum subject matter jurisdiction of this Superior Court according to proof at trial.

SIXTH CAUSE OF ACTION

(Negligent Misrepresentation)

- 69. Plaintiff realleges and incorporates the above referenced paragraphs as though fully set forth herein.
- 70. The Fentanyl Patch in question was originally formulated, designed, manufactured, marketed, and sold by Defendants.
- 71. At the time the Fentanyl Patch in question was sold, Defendants were in the business of formulating, designing, manufacturing, marketing, and selling products such as the one in question and knew that it would be used without inspection for defects.
- 72. Defendants from the time that the Fentanyl Patch at issue was first manufactured, marketed and distributed, and up to the present, made false misrepresentations, as previously set forth herein, to Darren Lee Baldwin, his physicians and the general public, including but not limited to, the misrepresentation that the Fentanyl Patch was safe, fit and effective for human use. At all times herein mentioned, the Defendants conducted a sales and marketing campaign to promote the sale of the Fentanyl Patch and willfully deceived Darren Lee Baldwin, his physicians and the general public as to the health risks and consequences of the use of Fentanyl Patches.
- 73. The Defendants made the foregoing representations without any reasonable ground for believing them to be true. These representations were made directly by the Defendants through their sales representatives and other authorized agents and in publications and other written materials directed to physicians: and medical patients, with the intention of inducing reliance and the purchase and use of the Fentanyl Patch prescription. The foregoing representations by the Defendants were in fact false, in that the Fentanyl Patch was not safe, fit and effective for human use, the

use of the Fentanyl Patch is hazardous to health, and has a serious propensity to cause serious injuries, including death, to users.

- 74. The foregoing representations by the Defendants were made with the intention 0 inducing reliance and the prescription, purchase and use of Fentanyl Patches.
- 75. In reliance on the misrepresentations by the Defendants, Darren Lee Baldwin was induced to purchase and use Fentanyl Patches. If Darren Lee Baldwin had known the true facts and the facts concealed by the Defendants he would not have used the Fentanyl Patch. The reliance of Darren Lee Baldwin upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.
- As a result of said negligence and carelessness of Defendants, Darren Lee Baldwin was caused to suffer a fatal overdose of the potent opioid, fentanyl, resulting in his death. As a direct and legal result of the conduct of Defendants, and each of them, severe and permanent injuries and damages were caused thereby to Plaintiff and Plaintiff's Decedent, including expenses for medical care, loss of earnings and earning capacity, loss of financial support, and loss of love, care, comfort, society, moral, assistance, and support, all in turn legally resulting in Plaintiffs special and general damages in a sum in excess of the minimum subject matter jurisdiction of this Superior Court according to proof at trial.

SEVENTH CAUSE OF ACTION

(Fraud and Deceit)

- 77. Plaintiff realleges and incorporates the above referenced paragraphs as though fully set forth herein.
- 78. The Fentanyl Patch in question was originally formulated, designed, manufactured, marketed, and sold by Defendants.
- 79. At the time the Fentanyl Patch in question was sold, Defendants were in the business of formulating, designing, manufacturing, marketing, and selling products

2.1

such as the one in question and knew that it would be used without inspection for defects.

- 80. Defendants, from the time that the Fentanyl Patch was first manufactured, marketed and distributed, and up to the present, willfully misrepresented, omitted material facts and deceived Darren Lee Baldwin by concealing from him, his physicians and the general public, the true facts concerning the Fentanyl Patch, which the Defendants, as manufacturer, maker and distributor of the products, had a duty to disclose.
- At all material times, the Defendants conducted a sales and marketing campaign to promote the sale of Fentanyl Patches and willfully deceived Darren Lee Baldwin, his physicians and the general public as to the health risks and consequences of the use of the Fentanyl Patch. The Defendants were aware of the foregoing, and that the Fentanyl Patch was not fit and effective for human use, the use of the Fentanyl Patch was hazardous to health, and that the Fentanyl Patch had a serious propensity to cause serious injuries to users, including but not limited to, death.
- 82. The Defendants intentionally misrepresented and omitted material facts, and concealed and suppressed the true facts concerning the Fentanyl Patch with the intent to defraud Darren Lee Baldwin, in that the Defendants knew that Darren Lee Baldwin's physicians would not prescribe the Fentanyl Patch and Darren Lee Baldwin would not have used the Fentanyl Patch, if they were aware of the true facts concerning the dangers of the Fentanyl Patch.
- 83. The Defendants made the above representations, which were untrue and known to be untrue or recklessly made such misrepresentations or omitted material facts, knowing they were material; the misrepresentations and omissions of material fact were done by the Defendants with intent to deceive potential users of the Fentanyl Patch, including Darren Lee Baldwin, which was done for the purpose of having potential users of the Fentanyl Patch, including Darren Lee Baldwin, act upon the misleading information or lack thereof. Darren Lee Baldwin did in fact, rely on such

misrepresentations or omissions by the Defendants, and Darren Lee Baldwin was induced thereby to act thereon in using the Fentanyl Patch which caused Darren Lee Baldwin's death.

As a result of said actions of Defendants, Darren Lee Baldwin was caused to suffer a fatal overdose of the potent opioid, fentanyl, resulting in his death. As a direct and legal result of the conduct of defendants, and each of them, severe and permanent injuries and damages were caused thereby to Plaintiff and Plaintiff's Decedent, including expenses for medical care, loss of earnings and earning capacity, loss of financial support, and loss of love, care, comfort, society, moral, assistance, and support, all in turn legally resulting in Plaintiffs special and general damages in a sum in excess of the minimum subject matter jurisdiction of this Superior Court according to proof at trial.

PUNITIVE DAMAGES

- 85. Plaintiff realleges and incorporates the above referenced paragraphs as though fully set forth herein.
- 86. The Fentanyl Patch in question was originally formulated, designed, manufactured, marketed, and sold by Defendants.
- 87. At the time the Fentanyl Patch in question was sold, Defendants were in the business of formulating, designing, manufacturing, marketing, and selling products such as the one in question and knew that it would be used without inspection for defects.
- 88. In committing the acts described above, Defendants were guilty of fraudulent, and/or malicious conduct.
- 89. Specifically, as alleged in detail above, Plaintiffs are informed and believe the Defendants, and each of them, designed, developed, assembled, manufactured, marketed advertised, purchased, inspected, repaired, serviced, distributed, and sold the product in question knowing that it was a defective and dangerous and likely to cause severe debilitating injuries, including fatal injuries, to users in foreseeable circumstances.

26

27

28

This conduct demonstrates a conscious disregard for the rights and safety of others, including Plaintiffs.

- 90. Defendants engaged in malice, fraud, and/or oppression with conscious disregard for the safety of consumers, including Darren Lee Baldwin, in the following particulars:
 - a. The Defendants researched, designed, formulated, compounded, tested, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, and/or advertised the Fentanyl Patch with knowledge that it was a dangerously defective product;
 - The Defendants failed to conduct, either directly or indirectly, adequate testing of the Fentanyl Patch after becoming aware of the dangers and risks facing those using the Fentanyl Patch;
 - c. The Defendants failed to adequately warn consumers and their treating physicians of the risk of patch failure and of suffering a fatal dose of fentanyl associated with use of the Fentanyl Patch;
 - d. The Defendants falsely and fraudulently misrepresented in their advertising, promotional materials and other materials, among things, the safety of using the Fentanyl Patch;
 - e. The Defendants knowingly omitted, suppressed or concealed material facts about the unsafe and defective nature of the Fentanyl Patch from the medical community and/or the consuming public;
 - f. The Defendants made the above representations, which were untrue and known to be untrue or recklessly made such misrepresentations, omitted material facts, knowing they were material, concerning the increased risks death due to overdose of fentanyl. Users did in fact, rely on such misrepresentations or omissions by the Defendants and users were induced thereby to act thereon in using the Fentanyl Patch which caused Darren Lee Baldwin's death;

- g. The Defendants acted negligently in marketing and selling the Fentanyl Patch and failing to timely remove it from the market;
- The Defendants actions constitute the production and sale of a defective and unreasonably dangerous product, a violation of Section 402A of the Restatement (Second) of Torts;
- The Defendants actions constitute negligence in the design and/or testing of the Fentanyl Patch, including negligent failure to warn;
- j. The Defendants failed to exercise reasonable care in designing, manufacturing and/or marketing the Fentanyl Patch to the public, including Darren Lee Baldwin:
- k. The Defendants delayed in informing users of the Fentanyl Patch of the increased risk of fatal overdose of fentanyl when using the Fentanyl Patch and thus precluded users, including Darren Lee Baldwin from making an informed decision on whether or not to use the Fentanyl Patch and risk serious injury; and
- I. The Defendant's actions justify an award of punitive damages.
- 91. Based on information and belief, the Defendants actually knew of the Fentanyl Patch's defective nature but continued to design, manufacture, market and sell the Fentanyl Patch so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the Fentanyl Patch. Such conduct was at all times relevant hereto ratified by the corporate management of the Defendants herein.
- 92. Accordingly, Plaintiffs should recover, in addition to actual damages, punitive and exemplary damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them,

as follows:

1	1.	For general damages according to proof;		
2	2.	For punitive and exemplary damages according to proof;		
3	3.	For special damages according to proof;		
4	4.	For medical and related expenses according to proof;		
5	5.	For loss of earnings and earning capacity according to proof;		
6	6.	For costs of suit incurred herein;		
7	7.	For interest on said judgment pursuant to law; and		
8	8.	For such other and further relief as the Court may deem just and proper.		
9				
10				
11				
12		/s/ Lee L. Coleman LEE L. COLEMAN TN Bar No. 019689		
13		Attorneys for Plaintiffs Hughes & Coleman		
14		P.O. Box 10120 Bowling Green, KY 42102		
15		Telephone: (270) 785-2110 Facsimile: (270) 782-8820		
16	OF COUNSEL FOR PLAINTIFF: TONY PLETCHER WATTS GUERRA CRAFT LAW FIRM Prosperity Bank Building 12 th Floor 500 North Water Street Corpus Christi, TX 78471 877-887-9433 Fax: 713-225-0566			
17				
18				
19				
20				
21	tpletcher@wgclawfirm.com			
22				
23				
24				
25				
26				
27				
28				
		20		